

1 **Amendment to the Claims**

2 **In the Claims:**

3 Please cancel Claims 4, 5, 24, 25, 53, and 58.

4 Please amend Claims 1, 21, 22, 23, 27, 52, 54, and 57; and add new Claim 59, as follows:

5 1. (Currently Amended) A medical simulator for training ultrasound operators to perform
6 cranosynostosis screenings using medical ultrasound, comprising a substantially life size model of a
7 human infant head, ~~said model being at least in part a skull portion of the model being primarily~~
8 ~~fabricated from a first material, said model skull portion including at least one simulated patent skull~~
9 ~~suture comprising a second material and a scalp portion in which each simulated patent skull suture is~~
10 ~~disposed, such that the scalp portion of the model is covered with a layer of the second material, the~~
11 ~~second material extending beyond an opening in the first material defining the simulated patent skull~~
12 ~~suture and covering at least a portion of the first material, to prevent the simulated patent skull suture~~
13 ~~from being identified tactilely, the second material having an echogenicity substantially different~~
14 lower than an echogenicity of said first material, such that each simulated patent skull suture can be
15 readily distinguished in an ultrasound image of said model, with portions of the model corresponding
16 to the first material appearing relatively brighter and portions of the model corresponding to the
17 second material appearing relatively darker in the ultrasound image, an interior volume of the model
18 being substantially empty.

19 2. - 6. (Canceled)

20 7. (Previously Presented) The medical simulator of Claim 1, wherein the second material
21 comprises a mixture of a starch and a glue.

22 8. (Original) The medical simulator of Claim 7, wherein the glue is a casein-based glue.

23 9. (Original) The medical simulator of Claim 7, wherein the glue is a synthetic resin-based
24 glue.

25 10. (Previously Presented) The medical simulator of Claim 1, wherein at least one simulated
26 patent skull suture corresponds to at least one of a simulated patent coronal skull suture and a
27 simulated patent lambdoid skull suture, and wherein each opening corresponding to a simulated
28 patent coronal skull suture is beveled, and each opening corresponding to a simulated patent
29 lambdoid skull suture is beveled.

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1 11. (Previously Presented) The medical simulator of Claim 1, wherein at least one opening
2 corresponding to a simulated patent skull suture corresponds to at least one of a simulated patent
3 sagittal skull suture and a simulated patent metopic skull suture, so that opposed walls of each
4 opening corresponding to a simulated patent sagittal skull suture exhibit an end-to-end configuration,
5 and opposed walls of each opening corresponding to a simulated patent metopic skull suture exhibit
6 an end-to-end configuration.

7 12. (Previously Presented) The medical simulator of Claim 1, further comprising at least one
8 simulated fused skull suture.

9 13. (Original) The medical simulator of Claim 12, wherein each simulated fused skull suture
10 comprises said first material.

11 14. (Previously Presented) The medical simulator of Claim 12, wherein each simulated fused
12 skull suture comprises an opening within said first material, each opening corresponding to a simulated
13 fused skull structure in which a third material is disposed, an echogenicity of the third material being
14 substantially distinguishable from the echogenicity of the second material, so that each opening
15 corresponding to a simulated fused skull suture can be readily distinguished from an opening
16 corresponding to a simulated patent skull suture in an ultrasound image of said model.

17 15. (Original) The medical simulator of Claim 14, wherein the echogenicity of the third
18 material is substantially similar to the echogenicity of the first material, such that in an ultrasound
19 image of the model, portions of the model comprising the first material are not readily distinguishable
20 from portions of the model comprising the third material.

21 16. (Original) The medical simulator of Claim 14, wherein the third material comprises a
22 synthetic elastomer.

23 17. (Original) The medical simulator of Claim 16, wherein the synthetic elastomer comprises
24 dimethyl siloxane, hydroxy-terminated polymers, and silica.

25 18. (Original) The medical simulator of Claim 12, further comprising an opaque layer
26 configured to cover each simulated patent skull suture and each simulated fused skull suture, so that a
27 trainee cannot readily visually determine whether a specific skull suture is patent or fused by visually
28 inspecting the model.

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1 19. (Original) The medical simulator of Claim 1, further comprising an opaque layer
2 configured to cover a scalp portion of the model, so that a trainee cannot readily visually locate each
3 simulated patent skull suture by visually inspecting the model.

4 20. (Original) The medical simulator of Claim 1, wherein a doll's head is utilized for the
5 substantially life size model of a human head.

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1 21. (Currently Amended) A reconfigurable medical simulator adapted to be used to train
2 ultrasound operators to perform craniosynostosis screenings using medical ultrasound, comprising:

3 (a) a substantially life size model of a human infant head, said model including a
4 plurality of skull suture openings disposed at locations corresponding to a skull suture;

5 (b) a quantity of a removable first material having an echogenicity such that when
6 the first material is disposed within an opening in the model corresponding to a skull suture, that
7 opening will appear as a patent skull suture in an ultrasound image of the model, the first material
8 comprising a solid or semi-solid hypoechoic material ~~being included in each opening so that the~~
9 ~~opening corresponds to a simulated patent skull suture, wherein the hypoechoic material causes an~~
10 ~~echogenicity of the simulated skull suture to differ from that of portions of the model not~~
11 ~~corresponding to the simulated patent skull suture, the difference enabling each simulated patent skull~~
12 ~~suture to be identified in an ultrasonic image; and~~

13 (c) a quantity of a removable second material having an echogenicity such that
14 when the second material is disposed within an opening in the model corresponding to a skull suture,
15 that opening will appear as a fused skull suture in an ultrasound image of the model, the second
16 material comprising an echogenic material, the second material having an echogenicity that is
17 substantially higher than an echogenicity of the first material, the first and second materials enabling a
18 user to selectively reconfigure the model by controlling which of the first and second materials are used
19 to fill specific openings, such that if an opening is filled with the first material to simulate a patent
20 skull suture and the user desires that opening to appear as a fused skull in an ultrasound image of the
21 model, the user removes the first material and fills the opening with the second material, such that the
22 opening will appear as a fused skull suture in an ultrasound image of the model, there being a
23 substantial difference in the echogenicities of the first and second materials, such that the first and
24 second materials are readily distinguishable in an ultrasound image, the first and second materials
25 being elements of the reconfigurable medical simulator ~~filler material for selectively replacing the~~
26 ~~hypoechoic material included in at least one selected opening, the filler material having an~~
27 ~~echogenicity that is generally similar to that of the portions of the model not corresponding to the~~
28 ~~simulated skull suture, so that each opening in which the filler material replaces the hypoechoic~~
29 ~~material simulates a fused skull suture in an ultrasonic image, the model being modifiable between~~
30 ~~training sessions by replacing the hypoechoic material with the filler material in at least one opening.~~

1 22. (Currently Amended) The medical simulator of Claim 21, wherein when the medical
2 simulator is imaged using ultrasound and at least one of the plurality of skull suture openings is filled
3 with the first material, the hypoechoic first material produces a relatively dark image, whereas
4 adjacent portions of the model produce a relatively bright image, such that each simulated patent
5 skull suture appears in the ultrasound image as a relatively dark area surrounded by relatively brighter
6 areas.

7 23. (Currently Amended) The medical simulator of Claim 21, wherein said model is
8 fabricated from a ~~first~~ third material having an echogenicity substantially corresponding to the
9 echogenicity of the second material and at least one of the plurality of skull suture openings is filled
10 with the second material to simulate a fused skull suture, such that ~~the solid or semi-solid hypoechoic~~
11 ~~material included in each opening corresponding to a simulated patent skull suture represents a~~
12 ~~second material, an echogenicity of the second material being substantially different than the~~
13 ~~echogenicity of the first material, so that each opening corresponding to a simulated patent~~ each
14 simulated fused skull suture ~~[[can]] cannot~~ be readily distinguished from the ~~first~~ third material in an
15 ultrasound image of said model.

16 24. (Canceled)

17 25. (Canceled)

18 26. (Previously Presented) The medical simulator of Claim 21, wherein:

19 (a) each opening corresponding to a simulated patent skull suture intended to
20 represent a patent coronal skull suture is beveled;

21 (b) each opening corresponding to a simulated patent skull suture intended to
22 represent a patent lambdoid skull suture is beveled;

23 (c) each opening corresponding to a simulated patent skull suture intended to
24 represent a patent sagittal skull suture is disposed such that opposed walls of the opening exhibit an
25 end-to-end configuration; and

26 (d) each opening corresponding to a simulated patent skull suture intended to
27 represent a patent metopic skull suture is disposed such that opposed walls of the opening exhibit an
28 end-to-end configuration.

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1 27. (Currently Amended) [[An]] A reconfigurable ultrasound trainer configured to train
2 ultrasound operators to perform craniosynostosis screenings using medical ultrasound[;],
3 comprising a substantially life size model of a human infant head, said model including at least one
4 replaceable simulated patent skull suture comprising a first material and at least one replaceable
5 simulated fused skull suture comprising a second material, an echogenicity of the first material being
6 substantially lower than an echogenicity of the second material, such that each replaceable simulated
7 patent skull suture enabling the simulated patent skull suture to be is readily distinguishable from
8 each replaceable simulated fused skull suture in an ultrasound image of said model, such that each
9 replaceable simulated patent skull suture will appear dark in such an ultrasound image, and each
10 replaceable simulated fused skull suture will appear bright in such an ultrasound image, each
11 replaceable simulated patent skull suture and each replaceable simulated fused skull suture being
12 interchangeable, such that a user can change the relative locations of each replaceable simulated
13 patent skull suture and each replaceable simulated patent skull suture to reconfigure the ultrasound
14 trainer.

15 28.-51. (Canceled)

16 52. (Currently Amended) A reconfigurable medical simulator for training ultrasound
17 operators to perform craniosynostosis screenings using medical ultrasound, comprising a
18 substantially life-size model of a human infant head, said model including two eyes, a mouth, two
19 ears, and ~~at least one simulated patent skull suture that can be selectively modified to appear as a~~
20 ~~simulated fused skull suture~~ a plurality of openings, each opening simulating a skull suture, at least
21 one of the plurality of openings being filled with a removable first material to simulate a patent skull
22 suture, and at least one of the plurality of openings being filled with a removable second material to
23 simulate a fused skull suture, an echogenicity of the removable first material being substantially
24 lower than an echogenicity of the removable second material, a difference in echogenicity of the
25 removable first material in each simulated patent skull suture and the removable second material in
26 each simulated fused skull suture enabling each simulated patent skull suture to be readily
27 distinguishable from non suture portions of the model and from each simulated fused suture in an
28 ultrasound image of said model, the removable first material and the removable second material
29 being interchangeable, such that a user can change the relative locations of each simulated patent
30 skull suture and each simulated fused skull suture to reconfigure the ultrasound trainer.

1 53. (Canceled)

2 54. (Currently Amended) A medical simulator for training ultrasound operators to perform
3 craniostynosis screenings using medical ultrasound, comprising a substantially life size model of a
4 human head, said model being at least in part fabricated from a first material, said model including:

5 (a) at least one simulated patent skull suture being at least in part fabricated from a
6 second material, said second material comprising at least one of a solid and a semi-solid, an
7 echogenicity of said second material being substantially ~~different~~ lower than an echogenicity of said
8 first material, such that each simulated patent skull suture can be readily distinguished in an
9 ultrasound image of said model; and

10 (b) at least one simulated fused skull suture, wherein each simulated fused skull
11 suture comprises an opening within said first material, a third material being disposed within each
12 opening corresponding to a simulated fused skull structure, an echogenicity of the third material
13 being substantially ~~distinguishable from~~ higher than the echogenicity of the second material, so that
14 each simulated fused skull suture can be readily distinguished from each simulated patent skull suture
15 in an ultrasound image of said model.

16 55. (Previously Presented) The medical simulator of Claim 54, wherein the echogenicity of
17 the third material is substantially similar to the echogenicity of the first material, such that in an
18 ultrasound image of the model, portions of the model comprising the first material are not readily
19 distinguishable from portions of the model comprising the third material.

20 56. (Previously Presented) The medical simulator of Claim 54, wherein the third material
21 comprises a synthetic elastomer.

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1 57. (Currently Amended) A medical simulator adapted to be used to train ultrasound
2 operators to perform craniosynostosis screenings using medical ultrasound, comprising a
3 substantially life size model of a human head, said model including:

4 (a) ~~a substantially life size model of a human head, said model including~~ at least
5 one opening corresponding to a simulated patent skull suture, a solid or semi-solid hypoechoic
6 material being disposed within each such opening to enhance a difference in an echogenicity of the
7 simulated skull suture relative to that of portions of the model not corresponding to the simulated
8 patent skull suture, the difference enabling each simulated patent skull suture to be identified in an
9 ultrasonic image, said model being fabricated from a first material, such that the solid or semi-solid
10 hypoechoic material disposed within each opening corresponding to a simulated patent skull suture
11 represents a second material, an echogenicity of the second material being substantially ~~different~~
12 lower than the echogenicity of the first material, so that each opening corresponding to a simulated
13 patent skull suture can be readily distinguished from the first material in an ultrasound image of said
14 model; and

15 (b) at least one opening corresponding to a simulated fused skull suture, a third
16 material being disposed within each opening corresponding to a simulated fused skull suture, an
17 echogenicity of the third material being substantially ~~different~~ higher than the echogenicity of the
18 second material, so that each opening corresponding to a simulated fused skull suture can be readily
19 distinguished from an opening corresponding to a simulated patent skull suture in an ultrasound
20 image of said model.

21 58. (Canceled)

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1 59. (New) A reconfigurable medical simulator adapted to be used to train ultrasound
2 operators to perform craniosynostosis screenings using medical ultrasound, comprising:

3 (a) a substantially life size model of a human infant head, said model including a
4 plurality of skull suture openings;

5 (b) a first material provided for use with the reconfigurable medical simulator to
6 enable a skull suture opening to appear as a patent skull suture in an ultrasound image of the
7 reconfigurable medical simulator when the first material is introduced into that opening, the first
8 material comprising a solid or semi-solid hypoechoic material, and the first material comprising a
9 mixture of starch and glue; and

10 (c) a second material provided for use with the reconfigurable medical simulator
11 to enable a skull suture opening to appear as a fused skull suture in an ultrasound image of the
12 reconfigurable medical simulator when the second material is introduced into that opening, the
13 second material comprising a material that is substantially more echogenic than the first material,
14 such that each skull suture opening filled with the first material can be readily distinguished from
15 each other skull suture opening filled with the second material in an ultrasound image, such that the
16 first and second materials can be selectively inserted into the skull suture openings before acquiring
17 the ultrasound image, the second material comprising a solid or semi-solid echoic material having an
18 echogenicity substantially similar to portions of the skull adjacent to the plurality of skull suture
19 openings, so that in the ultrasound image of the model each skull opening filled with the second
20 material is not substantially distinguishable from the portions of the skull adjunct to that opening,
21 there being a substantial difference in the echogenicities of the first and second materials, such that
22 the first and second materials are readily distinguishable in an ultrasound image, the first and second
23 materials being elements of the reconfigurable medical simulator, the second material comprising a
24 silicone based elastomer.